

Applicants: Nawaz Ahmad et al.

Serial No.: 10/696,939

Art Unit: 1796

Filed: October 30, 2003

Examiner: Edward Cain

For: WARMING AND NONIRRITATING LUBRICANT COMPOSITIONS  
AND METHOD OF COMPARING IRRITATION

**I hereby certify that this Submission Under 37 C.F.R. §1.99 and documents cited therein are being transmitted via The Office electronic filing system in accordance with 37 CFR 1.6(a)(4)**

**November 15, 2007  
(Date of Transmission)**

**Karin L. Williams, Reg. No. 36,721  
(Name of applicant, assignee, Registered Representative, or 3<sup>rd</sup> Party)**

**/Karin L. Williams/  
(Signature)**

**November 15, 2007  
(Date of Signature)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Nawaz Ahmad et al.

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For: **WARMING AND NONIRRITATING LUBRICANT COMPOSITIONS  
AND METHOD OF COMPARING IRRITATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

COPY

**SUBMISSION UNDER 37 C.F.R. § 1.99**

Sir:

In accordance with the provisions of 37 C.F.R. § 1.99, submitted herewith are publications that are relevant to the above-captioned pending patent application, which was published on July 15, 2004 as U.S. Patent Application Publication No. 2004/0138074 A1. Specifically, submitted herewith are copies of PAIR publications of documents from related co-pending Application Nos. 10/390,511 and 10/697,353.

As required by 37 C.F.R. § 1.99 and M.P.E.P. § 1134.01, the undersigned hereby:

(1) states that since (i) Amendment filed by Applicants in the above-captioned application on October 30, 2007 “change[d] the scope of the claims to an extent that could not reasonably have been anticipated by a person reviewing the published application during the period specified in 37 CFR 1.99(e)” (M.P.E.P. 1134.01(II)); and/or (ii) all of the currently submitted documents were published after the period specified in 37 C.F.R. § 1.99(e) expired, the publications could not have been submitted to the Office earlier, within two months of the July 15, 2004 publication date of the subject application;

(2) authorizes payment of the \$130.00 processing fee set forth in 37 C.F.R. § 1.17(i) to Deposit Account 50-1047;

(3) authorizes payment of the \$180.00 fee set forth in 37 C.F.R. § 1.17(p)) to Deposit Account 50-1047;

(4) lists nine publications submitted herewith:

(i) July 26, 2006 non-final Office Action in Application No. 10/390,511 (rejecting claims 20-24, 26-33 and 35 under 35 U.S.C. § 103(a) over JP 2-311408 in view of U.S. Patent Nos. 4,232,003 and 5,512,289)

(ii) December 22, 2006 Amendment in response to the July 26, 2006 Office Action in Application No. 10/390,511

(iii) April 2, 2007 final Office Action in Application No. 10/390,511 (rejecting claims 20-24, 26, 28-33, 35 and 36 under 35 U.S.C. § 103(a) over JP 2-311408 in view of U.S. Patent Nos. 4,232,003 and 5,512,289)

(iv) August 2, 2007 Amendment in response to the April 2, 2007 Office Action in Application No. 10/390,511

(v) October 12, 2007 Restriction Requirement in Application No. 10/390,511

(vi) November 5, 2007 Response to Restriction Requirement in Application No. 10/390,511

(vii) March 20, 2007 final Office Action in Application No. 10/697,353 (rejecting claims 20-23 and 26 under 35 U.S.C. 102(b), or in the alternative under 35 U.S.C. § 103(a), over the English language translation of JP 2-311408 or the English language translation of JP 2001-335429 or the English language translation of ES 2,074,030 or the English language abstract of

(viii) October 9, 2007 Notice of Abandonment in Application No. 10/697,353

(ix) English language translation of JP 2-311408<sup>1</sup>

(5) submits copies of nine documents listed above in accordance with 37 C.F.R. § 1.99(d);

(6) since all of the submitted publications are in English, no translations are required; and

(7) certifies that the information being submitted has been served in accordance 37 C.F.R. § 1.248 on the applicant's attorney at Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003 on November 15, 2007 by hand delivery, as shown by the attached copy of the Rule 1.99 submission signed by Johnson & Johnson Paralegal Kim Giganti which is acceptable as proof of service under 37 C.F.R. § 1.248(b).

In view of the above, it is respectfully submitted that this Submission complies with both timeliness and content requirements set forth in 37 C.F.R. § 1.99. Thus, the entire Submission should be forwarded to the Examiner for consideration.

The undersigned may be reached at the below listed address.

Date: November 15, 2007

Respectfully submitted,

/Karin L. Williams/  
Karin L. Williams, Reg. No. 36,721

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<sup>1</sup> First published by the European Patent Office (EPO) on or about July 25, 2005 in European Patent Application No. 03731070.3. This document may also be retrieved via the EPO's Online Public File Inspection service at <http://ofi.epoline.org>.

Received By: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

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COPY

WO 01/64176)

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Received By: Kim Giganti  
Name: Kim Giganti  
Title: Paralegal

Date: 11/15/07



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/390,511  | 03/17/2003  | Nawaz Ahmad          | PPC834CIP           | 2684             |
| 27777   | 7590        | 07/26/2006           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | VU, JAKE MINH       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1618                |                  |

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/390,511

Applicant(s)

AHMAD ET AL.

Examiner

Jake M. Vu

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-19, 25 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-24, 26-33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1618

### DETAILED ACTION

Receipt is acknowledged of Applicant's Response to Restriction/Election Requirement filed on 05/11/2006. Claims 1-35 are pending in the instant application. Claims 1-19, 25 and 34 are withdrawn from consideration.

#### *Election/Restrictions*

Applicant's election with traverse of Group I (claims 20-33 and 35) in the reply filed on 05/11/2006 is acknowledged. The traversal is on the ground(s) that search of all the Groups would pose no burden upon the Office. This is not found persuasive because searching all of the claims would require searching in numerous different subclasses, as well as a different searching focus depending on whether the product or method of use are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the "alkylene glycol" specie in the reply filed on 05/11/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, claim 25 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/11/2006.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-33 and 35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 7,005,408 and 5,885,591. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patents recited a method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition comprising polyhydric alcohol, insulating agent such as isopropyl myristate, wherein the composition convey a feeling of warmth upon application (see US 7,005,408 at claim 2). Wherein the polyhydric is an alkylene glycol (see claim 6), such as propylene glycol

(see claim 7). The composition further comprises a preservative (see claim 4), a bioadhesive agent (see claim 5) and honey (see claim 1).

The patent does not recite using a gelling agent such as hydroxyethylcellulose.

AKIYAMA disclosed a lubricant composition comprised of: a polyhydric alcohol, such as propylene glycol (see pg. 4), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or hydroxyethyl cellulose (see pg. 6); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate hydroxyethyl cellulose. The person of ordinary skill in the art would have been motivated to make those modifications, because it would give the composition the desired viscosity, and reasonably would have expected success because AKIYAMA had used this in a similar composition.

Claims 20-33 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082, 10/847083, and 11/299884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application recites a method of providing personal lubrication to a human's oral or vaginal mucosa during intercourse comprising applying to the oral or vaginal mucosa a composition comprising a

Art Unit: 1618

substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol (see Application 11/299884 at claim 19), where in the polyhydric alcohol is selected from the group consisting of alkylene glycol (see claim 21).

The copending claims do not recite using a gelling agent such as hydroxyethylcellulose.

AKIYAMA disclosed a lubricant composition comprised of: a polyhydric alcohol, such as propylene glycol (see pg. 4), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or hydroxyethyl cellulose (see pg. 6); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate hydroxyethyl cellulose. The person of ordinary skill in the art would have been motivated to make those modifications, because it would give the composition the desired viscosity, and reasonably would have expected success because AKIYAMA had used this in a similar composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-24, 26-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIYAMA et al (JP2-311408) in view of POSTHUMA (US 4,232,003) and TSENG et al (US 5,512,289).

Applicant claims are directed to a method of personal lubrication to a human's vaginal mucosa comprising applying a composition comprising: a polyhydric alcohol, such as propylene glycol; a gelling agent; a preservative; a bioadhesive agent; an insulating agent, such as isopropyl myristate.

AKIYAMA disclosed a composition comprised of: a polyhydric alcohol, such as 80% of propylene glycol (see pg. 4 and pg. 9, Working Example 5), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or 1% of hydroxyethyl cellulose (see pg. 6 and pg. 9, Working Example 5); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

Note, AKIYAMA disclosed "during massage, the force of the massage is transferred tangibly to the skin without causing excess peeling of the corneum due to friction" this would read on as a function of a lubricant.



AKIYAMA does not disclose using lactic acid in the composition or use the composition as a vaginal lubricant.

POSTHUMA disclosed, "Typical lubricants in use today as for vaginal use...constitute common lubricants such as petrolatum jelly, propylene glycol..." (see col. 1, line 28-31) and applying the lubricant to the vaginal area (see claim 1).

TSENG disclosed a vaginal lubricant comprised of: propylene glycol and hydroxyethyl cellulose (see col. 5, line 18 and col. 6, Example 1); a preservative, such as methyl paraben; and a pH adjuster such as lactic acid (see col. 11, line 17). Additional disclosure includes: the pH should be between 3-5.5 in order to be compatible with the vaginal mucosa (see col. 5, line 15-19).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate lactic acid as a pH adjuster into AKIYAMA's composition and use AKIYAMA's composition as lubrication for the vaginal area. The person of ordinary skill in the art would have been motivated to make that modification and reasonably would have expected success because AKIYAMA's composition is comprised of mostly propylene glycol, a commonly used vaginal lubricant in the prior art. Additionally, AKIYAMA disclosed the composition could be functioned as a lubricant (see pg. 11).

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a

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person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as viscosity and pH. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claim 27 is free of the art of record, because the prior art does not teach using honey as an insulating agent in lubrications. However, claim 27 is dependent on rejected claims.

#### ***Telephonic Inquiries***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD  
Art Unit 1618



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER

|                                   |                                       |  |             |
|-----------------------------------|---------------------------------------|--|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>10/390,511 | Applicant(s)/Patent Under<br>Reexamination<br>AHMAD ET AL. |             |
|                                   | Examiner<br>Jake M. Vu                | Art Unit<br>1618   | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name            | Classification |
|---|---|--|-----------------|-----------------|----------------|
| * | A | US-4,232,003                                     | 11-1980         | Posthuma et al. | 514/772.4      |
| * | B | US-5,512,289                                     | 04-1996         | Tseng et al.    | 424/426        |
|   | C | US-  |                 |                 |                |
|   | D | US-  |                 |                 |                |
|   | E | US-  |                 |                 |                |
|   | F | US-  |                 |                 |                |
|   | G | US-  |                 |                 |                |
|   | H | US-  |                 |                 |                |
|   | I | US-  |                 |                 |                |
|   | J | US-  |                 |                 |                |
|   | K | US-  |                 |                 |                |
|   | L | US-  |                 |                 |                |
|   | M | US-  |                 |                 |                |

**FOREIGN PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name           | Classification |
|---|---|--|-----------------|---------|----------------|----------------|
|   | N | JP 2-311408                                      | 12-1990         | Japan   | Akiyama et al. | A61K 7/00      |
|   | O |  |                 |         |                |                |
|   | P |  |                 |         |                |                |
|   | Q |  |                 |         |                |                |
|   | R |  |                 |         |                |                |
|   | S |  |                 |         |                |                |
|   | T |  |                 |         |                |                |

**NON-PATENT DOCUMENTS**

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
|   | U |   |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

DEC. 22. 2006 2:16PM

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DEC 22 2006

Docket No. PPC-834CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ahmad et al.  
Serial No. : 10/390,511  
Filed : March 17, 2003  
Title : WARMING AND NONIRRITATING LUBRICANT  
COMPOSITIONS AND METHOD OF COMPARING IRRITATION  
Art Unit : 1618  
Examiner : Jake Minh Vu

I hereby certify that this correspondence is being filed via  
teletype/transmitted to the US Patent and Trademark Office at (571) 273-8300 on

December 22, 2006

(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194

(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

December 22, 2006

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is respectfully submitted in response to an Office Action of July 26, 2006. It is timely filed in view of the petition for a two-month extension of time submitted concurrently herewith. Please consider the following remarks.

The Listing of Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

12/27/2006 HDEMESS1 00000062 100750 10390511

01 FC:1201 400.00 DA  
02 FC:1202 50.00 DA

Serial No. 10/390,511

**Listing of Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

1. (Original) A substantially anhydrous lubricant composition comprising at least one polyhydric alcohol and a gelling agent.
2. (Original) A composition according to claim 1 wherein said composition further comprises a pH adjustment agent.
3. (Original) A composition according to claim 1 wherein said polyhydric alcohol is selected from the group consisting of: glycerin, alkylene glycol, polyethylene glycol and a mixture thereof.
4. (Original) A composition according to claim 1 wherein said gelling agent is hydroxypropylcellulose.
5. (Original) A composition according to claim 3 wherein said alkylene glycol is selected from the group consisting of: propylene glycol, butylene glycol and hexalene glycol.
6. (Original) A composition according to claim 4 wherein said polyethylene glycol is selected from the group consisting of polyethylene glycol 300, polyethylene glycol 400 and a mixture thereof.
7. (Original) A composition according to claim 1 wherein said gelling agent is lactic acid.
8. (Original) A composition according to claim 5 wherein said composition comprises from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
9. (Original) A composition according to claim 1 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
10. (Original) A composition according to claim 1 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
11. (Original) A composition according to claim 1 which further comprises an antimicrobial agent.

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12. (Original) A composition according to claim 11 wherein said antimicrobial agent is an antifungal agent.
13. (Original) A composition according to claim 11 wherein said antimicrobial agent is an antibacterial agent.
14. (Original) A composition according to claim 11 wherein said antimicrobial agent is an antiviral agent.
15. (Original) A composition according to claim 1 wherein said composition further comprises a spermicide.
16. (Original) A composition according to claim 1 wherein said composition further comprises a local anesthetic.
17. (Currently amended) A method of treating ~~or preventing~~ dysmenorrhea comprising applying a composition according to claim 1 intravaginally.
18. (Original) A composition according to claim 1 wherein said composition increases in temperature upon exposure to moisture.
19. (Original) A composition according to claim 7 wherein the pH of said composition is adjusted to between about 2 and about 6.
20. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition comprising at least one polyhydric alcohol and a gelling agent, said composition conveying a feeling of warmth upon application.
21. (Previously presented) A method according to claim 20 wherein said composition further comprises a preservative.
22. (Previously presented) A method according to claim 20 wherein said composition further comprises a bioadhesive agent.
23. (Previously presented) A method according to claim 20 wherein said polyhydric alcohol is selected from the group consisting of: glycerin, alkylene glycol, polyethylene glycol and a mixture thereof.
24. (Previously presented) A method according to claim 23 wherein said alkylene glycol is selected from the group consisting of: propylene glycol, butylene glycol and hexalene glycol.

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25. (Previously presented) A method according to claim 24 wherein said polyethylene glycol is selected from the group consisting of polyethylene glycol 300, polyethylene glycol 400 and a mixture thereof.
26. (Previously presented) A method according to claim 20 wherein said composition further comprises an insulating agent.
27. (Currently amended) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition comprising at least one polyhydric alcohol and a gelling agent, said composition conveying a feeling of warmth upon application wherein said composition further comprises an insulating agent, A method according to claim 26 wherein said insulating agent is honey.
28. (Previously presented) A method according to claim 20 wherein said composition comprises from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
29. (Previously presented) A method according to claim 20 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
30. (Previously presented) A method of providing personal lubrication to a human's oral or vaginal mucosa comprising applying to the oral or vaginal mucosa a composition comprising a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent comprising a water-soluble cellulose-derived film-forming polymer.
31. (Previously presented) A method according to claim 30 wherein said water-soluble cellulose-derived film-forming polymer is a hydroxyalkylcellulose polymer.
32. (Previously presented) A method according to claim 31 wherein said hydroxyalkylcellulose polymer is selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.
33. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition



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comprising a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

34. (Previously presented) A substantially anhydrous lubricant composition comprising at least one polyhydric alcohol and a gelling agent.

35. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition consisting essentially of a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

36. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition consisting essentially of a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

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REMARKS

This paper is respectfully submitted in response to an Office Action of July 26, 2006. It is timely filed in view of the petition for a two-month extension of time submitted concurrently herewith. With this extension, the due date for responding to the Office Action is December 26, 2006. Please consider the following remarks.

Claims 1-19 were originally filed in the present application. Claim 36 is newly presented. It finds basis in the Specification in the original claims and at p.13, l. 19-p. 14, l. 12 and p. 16, l. 20-25. Claim 27 has been rewritten to incorporate the subject matter of the claims from which it depends. No new matter has been added in the amendments to the claims.

The Office Action of July 26, 2006 made final the restriction requirement and the applicants' election of species. Apparently, applicants' traverse of the requirement for election was inadvertently ambiguous and had been intended to extend both to the restriction requirement and the election requirements.

The Office Action of July 26, 2006 rejected claims 20-33 and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patents Nos. 7,005,408 and 5,885,591. Applicants respectfully submit that U.S. Patent No. 5,885,591 relates to aqueous compositions and, therefore, is inappropriate as a cited reference hereunder. Should claims be allowed in this application, applicants will submit a terminal disclaimer in view of U.S. Patent No. 7,005,408 and, if necessary, in view of U.S. Patent No. 5,885,591, as well as over copending applications Serial Nos. 10/389,871, 10/390,511, 10/696,939, 10/697,353, 10/697,838, 10/847,082, 10/847,083 and 11/299,884.

The Office Action of July 26, 2006 also cites Akiyama in connection with the foregoing double patenting rejection. Applicants will discuss Akiyama in relation to the art rejections set forth below.

The Office Action of July 26, 2006 rejected claims 20-24, 26-33 and 35 under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al....in view of Posthuma...and Tseng et al. The basis for this rejection is as follows:

AKIYAMA disclosed a composition comprised of: a polyhydric alcohol...which feels warm to the touch...; a gelling agent, such as carboxyvinyl polymer...or 1% of

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hydroxyethyl cellulose...; a preservative...; a bioadhesive agent...; and an insulating agent...

POSTHUMA disclosed, "Typical lubricants in use today as for vaginal use...constitute common lubricants such as petrolatum jelly, propylene glycol..." and applying the lubricant to the vaginal area...

TSENG disclosed a vaginal lubricant comprised of: propylene glycol and hydroxyethyl cellulose...; a preservative...; and a pH adjuster...

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate lactic acid as a pH adjuster into AKIYAMA's composition and use AKIYAMA's composition as lubrication for the vaginal area. The person of ordinary skill in the art would have been motivated to make that modification and reasonably would have expected success because AKIYAMA's composition is comprised of mostly propylene glycol, a commonly used vaginal lubricant in the prior art. Additionally, AKIYAMA disclosed the composition could be functioned as a lubricant...[Office Action, p. 7]

Applicants respectfully request reconsideration of the foregoing rejection of claims 20-24, 26-33 and 35 under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al. in view of the ensuing remarks.

Akiyama et al. relates to a massage product that contains "an anionic polymer compound and a water-soluble non-ionic polymer compound...in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater." [Akiyama et al. translation, p. 2] Thus, Akiyama et al requires the presence of *both* an anionic polymer (such as a polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer) [Akiyama et al., p. 5] *and* a water-soluble non-ionic polymer compound (which might include hydroxyethyl cellulose) [Akiyama et al., p. 6]. In fact, Akiyama et al. suggests that using an anionic polymer compound is important to the composition: "If less than 0.1 wt% is used, *gel formation is poor*." [Akiyama et al., p. 5] (emphasis added) Thus, Akiyama et al. *requires* the presence of both an anionic polymer and a water-soluble non-ionic polymer. In contrast, the compositions of applicants' invention do not contain an anionic polymer.

Applicants also respectfully submit that one of ordinary skill in the art would not have been motivated to combine Akiyama et al. with either Posthuma or Tseng et al. Both Posthuma and Tseng et al. relate to *aqueous* compositions and do not compensate for the

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insufficiencies of Akiyama et al. in leading one of ordinary skill in the art to the compositions of applicants' invention.

Even if one were to have combined Akiyama et al. with either Posthuma or Tseng et al., one of ordinary skill in the art would not have arrived at the compositions or methods of applicants' invention as these both teach compositions containing a high percentage of water. Thus, such compositions would not achieve a warming reaction when applied to the skin.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of July 26, 2006. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

/Andrea L. Colby/

By: \_\_\_\_\_

Andrea L. Colby  
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DATE: December 22, 2006



# UNITED STATES PATENT AND TRADEMARK OFFICE

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|   |             |                      |                           |                  |
|---|-------------|----------------------|---------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
| 10/390,511  | 03/17/2003  | Nawaz Ahmad          | PPC834CIP                 | 2684             |
| 2777 7590 04/02/2007<br>PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | EXAMINER<br>VU, JAKE MINH |                  |
|   |             |                      | ART UNIT<br>1618          | PAPER NUMBER     |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE             |                  |
| 3 MONTHS  |             | 04/02/2007           | PAPER                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/390,511

Applicant(s)

AHMAD ET AL.

Examiner

Jake M. Vu

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-19, 25 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-24, 26-33, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 35 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 12/22/2006. Claim 36 has been added. Claims 1-36 are pending in the instant application. Claims 1-19, 25 and 34 have been previously withdrawn from consideration.

### *Claim Objections*

Claims 35 and 36 are objected to because of the following informalities: both claims are identical claims. Appropriate correction is required.

### *Double Patenting*

Claims 20-24, 26-33, 35 and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 7,005,408 **is maintained** for reasons of record in the previous office action filed on 07/26/2006.

Claims 20-24, 26-33, 35 and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 5,885,591 **is withdrawn** in view of Applicant's argument filed on 12/22/2006.

Claims 20-24, 26-33, 35 and 36 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082,

Art Unit: 1618

10/847083, and 11/299884 are maintained for reasons of record in the previous office action filed on 07/26/2006.

It is acknowledged that should any claims be allowed in this application, Applicant will file terminal disclaimers in view of U.S. Patent No. 7,005,408; and Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082, 10/847083, and 11/299884.

***Claim Rejections - 35 USC § 103***

Claims 20-24, 26, 28-33, 35 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over AKIYAMA et al (JP2-311408) in view of POSTHUMA (US 4,232,003) and TSENG et al (US 5,512,289) are maintained for reasons of record in the previous office action filed on 07/26/2006.

Claim 27 is free of the art of record, because the references do not teach using honey as an insulating agent.

***Response to Arguments***

Applicant argues that AKIYAMA requires the presence of both an anionic polymer and a water-soluble non-ionic polymer; in contrast, the compositions of Applicant's invention do not contain an anionic polymer. The Examiner finds this argument unpersuasive, because Applicant uses "comprises" in the claim language, which is open-ended language. Thus, Applicant's claims could contain anionic polymer.



In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this instance, Applicant argues that one of ordinary skill in the art would not have been motivated to combine AKIYAMA with either POSTHUMA or TSENG since the later references relate to aqueous compositions and do not compensate for the insufficiencies of AKIYAMA in leading one of ordinary skill in the art to the compositions of Applicant's invention. The Examiner finds this argument unpersuasive, because POSTHUMA disclosed that propylene glycol, which is in the AKIYAMA reference and Applicant's claims, are common lubricant used in the vagina. While the TSENG reference disclosed that pH adjusters, such as lactic acid are commonly used to adjust the pH of lubricants. Thus, it would have been obvious to the person of ordinary skill in the art to use AKIYAMA's lubricant as a vaginal lubricant with lactic acid as a pH adjuster.

Applicant argues that even if one were to have combined AKIYAMA with either POSTHUMA or TSENG, one of ordinary skill in the art would not have arrived at the composition or methods of Applicant's invention as these both teach compositions containing a high percentage of water. Thus, such composition would not achieve a warming reaction when applied to the skin. The Examiner finds this argument unpersuasive, because the primary reference, AKIYAMA, teaches the same composition as claimed by Applicant as a lubricant for massaging. Additionally,

AKIYAMA disclosed the lubricant "feels warm to the touch when used because of heat from the hydration reaction with the water content of the skin" (see pg. 4). Thus, such composition does achieve a warming reaction when applied to the skin.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

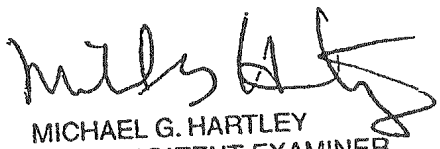
### ***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD  
Art Unit 1618

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Ahmad et al.  
Serial No. : 10/390,511  
Filed : March 17, 2003  
Title : WARMING AND NONIRRITATING LUBRICANT  
COMPOSITIONS AND METHOD OF COMPARING IRRITATION  
Art Unit : 1618  
Examiner : Jake Minh Vu

I hereby certify that this correspondence is being filed via  
The Office electronic filing system in accordance with 37 CFR 1.6(a)(4) on  
August 2, 2007  
(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194  
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

August 2, 2007  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

Dear Sir:

This paper is respectfully submitted in response to the Final Rejection of April 2, 2007. It is timely filed in view of the petition for a one-month extension of time submitted concurrently herewith. Applicants also respectfully submit a Request for Continued Examination concurrently herewith. Please consider the following remarks.

The Listing of Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

**Listing of Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

Claims 1-36 (Canceled)

37. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
38. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
39. (New) A substantially anhydrous personal lubricant composition consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
40. (New) A composition according to claim 37 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
41. (New) A composition according to claim 37 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
42. (New) A method according to claim 20 wherein said composition further comprises a preservative.
43. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid, said composition conveying a feeling of warmth upon application.
44. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition

consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.

45. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
46. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof and hydroxypropylcellulose.
47. (New) A composition according to claim 46 wherein said composition further comprises honey.
48. (New) A composition according to claim 46 wherein said polyhydric alcohols present are propylene glycol and polyethylene glycol.
49. (New) A composition according to claim 48 wherein said polyhydric alcohols are present in the amount of from about 75% to about 99% by weight and said hydroxypropylcellulose is present in the amount of from about 0.1% to about 4% by weight of the composition.

REMARKS

This paper is respectfully submitted in response to the Office Action of April 2, 2007. It is timely filed in view of the petition for a one-month extension of time submitted concurrently herewith. With this extension, the due date for responding to the Office Action is August 2, 2007. Applicants also respectfully submit a Request for Continued Examination concurrently herewith. Please consider the following remarks.

Claims 1-36 have been canceled without prejudice. Claims 37-49 have been added in order to expedite prosecution herein. New claims 37-49 find basis in the original claims and in the Specification at p. 13, l. 19-p. 14, l. 12 and p. 16, l. 20-25. No new matter has been added in the amendments to the claims.

In the Final Rejection of April 2, 2007, Claims 35 and 36 were objected to because of the following informalities: both claims are identical claims. As claims 35 and 36 have been canceled without prejudice, applicants respectfully submit that this objection is moot.

The Final Rejection of April 2, 2007 rejected claims 20-24, 26-33, 35 and 36 on the ground of nonstatutory obviousness-type double-patenting as being unpatentable over U.S. Patent Nos. 7,005,408. This rejection was maintained for reasons of record in the previous office action of 07/26/2006. Applicants respectfully offer that, should claims be allowed in this application, they will submit a terminal disclaimer in view of U.S. Patent No. 7,005,408 as well as Applications Nos. 10/389871, 10/390511, 10/696939, 10/697353, 10/697848, 10/847082, 10/847083, and 11/299884.

The Final Rejection of April 2, 2007 rejected claims 20-24, 26, 28-33, 35 and 36 under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al (JP2-311408) in view of Posthuma (US 4,232,003) and TSENG et al (US 5,512,289). The basis for rejection was maintained from the previous office action of July 26, 2006. The Office Action of April 2, 2007 responded to applicants' previous arguments as follows:

Applicant argues that AKIYAMA requires the presence of both an anionic polymer and a water-soluble non-ionic polymer; in contrast, the compositions of Applicant's invention do not contain an anionic polymer. The Examiner finds this argument unpersuasive, because Applicant uses "comprises" in the claim language, which is open-ended language. Thus, Applicant's claims could contain anionic polymer.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking the references individually where the rejections are based on combinations of references...In this instance, Applicant argues that one of ordinary skill in the art would not have been motivated to combine AKIYAMA et al. with either POSTHUMA or TSENG since the later references relate to aqueous compositions and do not compensate for the insufficiencies of AKIYAMA in leading one of ordinary skill in the art to the compositions of Applicant invention. The Examiner finds this argument unpersuasive, because POSTHUMA disclosed that propylene glycol, which is in the AKIYAMA reference and applicant's claims, are common lubricant used in the vagina. While the TSENG reference disclosed that pH adjusters, such as lactic acid are commonly used to adjust the pH of lubricants. Thus, it would have been obvious to the person of ordinary skill in the art to use AKIYAMA'S lubricant as a vaginal lubricant with lactic acid as a pH adjuster.

Applicant argues that even if one were to have combined AKIYAMA with either POSTHUMA or TSENG, one of ordinary skill in the art would not have arrived at the composition or methods of Applicant's invention as these both teach compositions containing a high percentage of water. Thus, such composition would not achieve a warming reaction when applied to the skin. The examiner finds this argument unpersuasive, because the primary reference, AKIYAMA, teaches the same composition as claimed by Applicant as a lubricant for massaging. Additionally, AKIYAMA disclosed the lubricant "feels warm to the touch when used because of heat from the hydration reaction with the water content of the skin. Thus, such composition does achieve a warming reaction when applied to the skin. [Office Action, p. 3-5]

Applicants respectfully request reconsideration of the foregoing rejection with respect to the newly-added claims and in light of the ensuing discussion.

Applicants respectfully note that claims 20-24, 26, 28-33, 35 and 36 have been canceled without prejudice in order to expedite prosecution herein. Applicants respectfully request consideration of the newly-added claims 37-49 in light of the following remarks. Applicants respectfully submit that Akiyama et al. relates to a massage product that contains "*an anionic polymer compound and a water-soluble non-ionic polymer compound...in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater.*" [Akiyama et al. translation, p. 2] (emphasis added) Thus, Akiyama et al requires the presence of *both* an anionic polymer (such as a polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer) [Akiyama et al., p. 5] *and* a water-soluble non-ionic polymer compound (which might include hydroxyethyl cellulose) [Akiyama et al., p. 6]. In fact, Akiyama et al. suggests that using an



anionic polymer compound is important to the composition: "If less than 0.1 wt% is used, *gel formation is poor.*" [Akiyama et al., p. 5] (emphasis added) Thus, Akiyama et al. *requires* the presence of both an anionic polymer and a water-soluble non-ionic polymer. In contrast, the compositions of applicants' invention as set forth in newly-added claims 37-49 do not contain an anionic polymer. Thus, Akiyama does *not* teach the same composition as those claimed by applicants and, rather, teaches away from such compositions.

Although the Office Actions have cited Posthuma for indicating that propylene glycol may be used in vaginal lubricant compositions, applicants respectfully note that Posthuma teaches that propylene glycol is *not preferred* for such usage:

Typical lubricants in use today as for vaginal use do not possess [sic] special characteristics rendering them particularly suitable for this usage, but rather constitute common lubricants such as petrolatum jelly, *propylene glycol, glycerine, and methyl cellulose.* These lubricants have characteristics different from those of normal mucus and consequently are *less than totally satisfactory* for physiological usage. [Posthuma, col. 1, l. 28-35] (emphasis added)

Applicants respectfully submit that the mere mention of an ingredient in a patent or publication should be taken in the context of such publications in order to determine what the publication would have taught one of ordinary skill in the art at the time of invention. With that consideration in mind, Posthuma clearly teaches away from utilizing propylene glycol in vaginal applications.

Likewise, Tseng et al. relates to a lubricating *spermicidal* composition that requires the presence of a "solubilizer" in the formulation in order "to permit the spermicide to be compatible with the water-soluble polymeric matrix." [Tseng, et al., col. 2, l. 10-11] While propylene glycol and lactic acid appear in the Tseng et al. patent, the compositions described therein must contain *in addition* not only a spermicide, but "ethoxylated esters or ethers, or ethoxylated fatty acid derivatives wherein the fatty acid moiety contains between 8 and 16 carbon atoms" [Tseng, et al., col. 4, l. 16-20] as well as a substantial amount of water. Thus, applicants respectfully submit that Tseng, et al., alone or in combination, would not have taught one of ordinary skill in the art toward the compositions and methods of applicants' invention.

Applicants also respectfully submit that, notwithstanding the case law noted in the Office Action with regard to consideration of the references individually, applicants are

permitted to review all references for the teachings therein in order to determine if they would have taught one of ordinary skill in the art toward the compositions and methods of applicants' invention.

In light of the foregoing remarks, applicants respectfully request consideration of newly-added claims 37-49 and reconsideration of the rejection under 35 U.S.C. §103(a). Applicants respectfully submit that the combination of Posthuma, Tseng et al. and Akiyama would not have led one of ordinary skill in the art to the compositions of applicants' invention.

Therefore, applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

/Andrea L. Colby/

By: \_\_\_\_\_  
Andrea L. Colby  
Attorney for Applicants  
Reg. No. 30,194

Johnson & Johnson  
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New Brunswick, NJ 08933-7003  
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DATE: August 2, 2007



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/390,511

03/17/2003

Nawaz Ahmad

PPC834CIP

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10/12/2007

PHILIP S. JOHNSON

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/390,511

Applicant(s)

AHMAD ET AL.

Examiner

Jake M. Vu

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-49 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 37-41 and 45-49, drawn to an anhydrous personal lubricant composition, classified in class 424, subclass 488.
- II. Claims 42-44, drawn to a method of providing personal lubrication to a human's vaginal mucosa, classified in class 514, subclass 57.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used as a lotion for back massages.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: viscosity of 1,000cps to about 7,000cps, and 60,000cps to about 500,000cps.

Art Unit: 1618

The species are independent or distinct because these are different ranges of viscosity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

Art Unit: 1618

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD  
Art Unit 1618

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a stylized, flowing script.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Ahmad et al.  
Serial No. : 10/390,511  
Filed : March 17, 2003  
Title : WARMING AND NONIRRITATING LUBRICANT  
COMPOSITIONS AND METHOD OF COMPARING IRRITATION  
Art Unit : 1618  
Examiner : Jake Minh Vu

I hereby certify that this correspondence is being filed via  
The Office electronic filing system in accordance with 37 CFR 1.6(a)(4) on  
November 5, 2007  
(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194  
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

November 5, 2007  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir:

This Response to Restriction Requirement is respectfully submitted in response to the Office Action of October 12, 2007. It is timely in view of the one-month shortened statutory period for response.

Status of the Claims is reflected on page 2 of this paper.

Remarks are reflected on page 6 of this paper.

**Listing of Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

Claims 1-36 (Canceled)

37. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
38. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
39. (New) A substantially anhydrous personal lubricant composition consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
40. (New) A composition according to claim 37 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
41. (New) A composition according to claim 37 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
42. (New) A method according to claim 20 wherein said composition further comprises a preservative.
43. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid, said composition conveying a feeling of warmth upon application.
44. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition

consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.

45. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
46. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof and hydroxypropylcellulose.
47. (New) A composition according to claim 46 wherein said composition further comprises honey.
48. (New) A composition according to claim 46 wherein said polyhydric alcohols present are propylene glycol and polyethylene glycol.
49. (New) A composition according to claim 48 wherein said polyhydric alcohols are present in the amount of from about 75% to about 99% by weight and said hydroxypropylcellulose is present in the amount of from about 0.1% to about 4% by weight of the composition.

REMARKS

This Response is respectfully submitted in response to the Office Action of October 12, 2007. The Office Action required restriction to one of the following inventions under 35 U.S.C. 121:

I. Claims 37-41 and 45-49, drawn to an anhydrous personal lubricant composition, classified in class 424, subclass 488.

II. Claims 42-44, drawn to a method of providing personal lubrication to a human's vaginal mucosa, classified in class 514, subclass 57.

The Office Action noted that:

Inventions I and II are related as product and process of use...In the instant case the product can be used as a lotion for back massages.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search..., restriction for examination purposes as indicated is proper. [Office Action, p. 2]

The Office Action further indicates that an election of species is required between "the following patentably distinct species: viscosity of 10,000cps to about 7,000cps, and 60,000cps to about 500,000cps" [Office Action, p. 2]. Applicants respectfully respond to the restriction requirement and species election as follows.

Applicants respectfully provisionally elect the inventions of Group I, with traverse. Applicants respectfully submit that the searching of these two Groups of claims should not entail a burden upon the Patent and Trademark Office. Applicants therefore respectfully request reconsideration of the restriction requirement.

Applicants, having provisionally elected the claims of Group I, respectfully elect the species defined as follows: 1,000cps to about 7,000cps.. Applicants believe that Claims 37-41 and 45-49 read thereon.

Serial No. 10/390,511

An early allowance is earnestly solicited.

Respectfully submitted,

/Andrea L. Colby/

---

Andrea L. Colby  
Attorney for Applicants  
Reg. No. 30,194

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One Johnson & Johnson Plaza  
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November 5, 2007



# UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/697,353      | 10/30/2003  | Nawaz Ahmad          | PPC-834-CIP-4       | 7581             |

27777 7590 03/20/2007  
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NEW BRUNSWICK, NJ 08933-7003

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| EXAMINER |
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ANTHONY, JOSEPH DAVID

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1714

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/20/2007 | PAPER         |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/697,353

Applicant(s)

AHMAD ET AL.

Examiner

Joseph D. Anthony

Art Unit

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18, 19 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23 and 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**FINAL REJECTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative as being rejected under 35 U.S.C. 103(a) as being obvious over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176.

Akiyama et al., Osamu et al., Carreras et al. and WO all directly teach anhydrous or substantially anhydrous gel or gel-like therapeutic topical compositions for use on the human body such as the skin. The said therapeutic topical compositions comprise at least one polyol, such as propylene glycol, polyethylene glycol, glycerin or the like. The thickening agent can be hydroxyethyl cellulose or the like. Additional adjuvants well known in be used in therapeutic topical compositions, such as antimicrobial agents, anti-inflammatory agents, anti-septics, pH regulators, etc., can optionally be added to said compositions. All said therapeutic topical compositions are disclosed to generate heat of solution when they are brought in contact with moisture such as water. See at least the abstracts, examples and claims of each reference. Applicant's claims are deemed to be anticipated over the said disclosures and examples of each individual reference.

invention also relates to methods of using such compositions for lubrication, administration of active ingredients and for preventing or treating dysmenorrhea. Applicant's claims are deemed to be anticipated over the examples of the patent, see abstract, examples and claims. Applicant's attention is drawn to the fact that applicant's specification in Example 9 directly teaches compositions 1-9 that are asserted by applicant to be composition of the invention, as such they must be compositions that meet the limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a Energy Release index of at least about 11 mJ/mg". Since the Ahmad et al patent directly teaches the same compositions 1-9, see columns 11-12, the Ahmad et al compositions must inherently meet applicant's claimed performance limitations.

NOTE: the examiner is well aware that applicant's pending application is a CIP application of S.N. 10/137,509 Now U.S. Patent Number 7,005,408. The new matter in all of applicant's claims is deemed to be the limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a Energy Release index of at least about 11 mJ/mg". As such, the effective filing date of applicant's pending claims is 10/30/2003 which is the actual filing date of the present application. Since the filing date of U.S. Patent Number 7,005,408 is 05/01/2002, the patent qualifies as prior-art under 35 U.S.C. 102(e).

In the alternative, applicant's claims may be said to "differ" from Ahmad et al. in that the patent does not directly state in writing applicant's claimed limitation of: "wherein said composition increases in temperature by at least about 5°C upon

exposure to moisture and which has a Energy Release index of at least about 11 mJ/mg. Although, applicant's said limitation is not directly stated in writing, it is nevertheless deemed to be obvious to one having ordinary skill in the art to make compositions that meet applicant's claimed performance requirements, using the disclosure of the patent as motivation because: 1) the patent teaches therapeutic topical compositions that contain the same components as applicant's compositions in approximately the same concentration ranges, 2) the patent teaches that the therapeutic topical compositions generate heat of solution when brought in contact with moisture, 3) the patent teaches that the use of there therapeutic topical compositions is for application to human skin and/or mucosal surfaces which by its very nature would require certain performance characteristic and limits to the amount of heat generated., and 4) applicant have set forth no showing of any criticality and/or superior and unobvious results for their claimed performance limitations.

### ***Double Patenting***

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 20-23 and 25-26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15, 19-22 and 24 of copending Application No. 10/696,939. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 20-23 and 25-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 15, and 19-24 of U.S. Patent No. 7,005,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the claimed subject matter.

9. Claims 20-23 and 25-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 of copending Application No. 10/697,383; as being unpatentable over claims 24-28 of copending Application No. 10/389,871; as being unpatentable over claims 20-35 of copending Application No. 10/390,511; and as being unpatentable over claims 15 and 19-23 of copending Application No. 11/299,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims in the present application are deemed to be a subset of the pending claims in said other pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

10. Applicant's arguments filed 12/18/06 with the amendment have been fully considered but are not persuasive to put the application in condition for allowance for the reasons set forth above. Additional examiner comments are set forth next.

The examiner has dropped the previously made prior-art rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176. The reasons for

this drop is that the examiner has now concluded that there is insufficient support within these references to reject applicant's claimed process of treating dysmenorrhea.

Applicant's amendment of "during intimate activities" incorporated into independent claims 21-23 and new claim 26, is not deemed to overcome the prior-art rejections made over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176, because: 1) the metes and bounds of the phrase "during intimate activities" is completely undefined and 2) according to applicant's own disclosure, applying the composition directly to skin can be considered to be a form of intimate activities.

Finally, applicant's assertion that the applied Ahmad et al. U.S. Patent Number 7,005,408 should be dropped because it is not to another is totally rejected by the examiner because it such is clearly a false statement. Applicant's claimed application has 6 listed inventors whereas Ahmad et al. U.S. Patent Number 7,005,408 has only 3 listed inventors of which only Nawaz Ahmad is a common inventor. As such, Ahmad et al. U.S. Patent Number 7,005,408, clearly has a different inventive entity than applicant's claimed application.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Examiner Information***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (571) 273-8300. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.



Joseph D. Anthony  
Primary Patent Examiner  
Art Unit 1714

3/15/07



# UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/697,353      | 10/30/2003  | Nawaz Ahmad          | PPC-834-CIP-4       | 7581             |

27777 7590 10/09/2007  
PHILIP S. JOHNSON  
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| EXAMINER |
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ANTHONY, JOSEPH DAVID

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1714

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|-----------|---------------|

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



# Examiner-Initiated Interview Summary

Application No.

10/697,353

Applicant(s)

AHMAD ET AL.

Examiner

Joseph D. Anthony

Art Unit

1714

## All Participants:

(1) Joseph D. Anthony.

(2) Angela Randel (assistant to Andrea L. Colby).

Status of Application: \_\_\_\_\_

(3) \_\_\_\_\_

(4) \_\_\_\_\_

Date of Interview: 28 September 2007

Time: \_\_\_\_\_

## Type of Interview:

☒ Telephonic

☐ Video Conference

☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☐ No

If Yes, provide a brief description:

## Part I.

Rejection(s) discussed:

Claims discussed:

Prior art documents discussed:

## Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:

*Ms. Randel said case has been let gone abandoned.*

## Part III.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

  
(Examiner/SPE Signature)

9/28/07  
(Applicant/Applicant's Representative Signature -- if appropriate)

# Notice of Abandonment

Application No.

10/697,353

Examiner

Joseph D. Anthony

Applicant(s)

AHMAD ET AL.

Art Unit

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 20 March 2007.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

*Joseph D. Anthony*

Joseph D. Anthony  
Primary Examiner  
Art Unit: 1714

9/25/07

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

[Translation from Japanese]

(19) Japanese Patent Office (JP)

(12) Official Gazette of Unexamined Patent Applications (A)

(11) Patent Application Publication Number: 2-311408

(43) Patent Application Publication Date: December 27, 1990

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|--|---------------------|--------------------|
| (51) Int. Cl. <sup>5</sup>                 | Identification Code | Internal File Nos. |
| A 61 K 7/00                                | R                   | 8413-4C            |
| Request for Examination: Not Yet Requested |                     |                    |
| Number of Claims: 2                        |                     | (Total of 5 Pages) |

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(54) Title of the Invention: **Gelatinous Composition for Skin**

(21) Application Number: 1-133763

(22) Application Date: May 25, 1989

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(74) Agent: Yoshihiro KIYOHARA, Patent Attorney

## Specification

### 1. Title of the Invention

#### **Gelatinous Composition for Skin**

### 2. Claims

(1) A gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater.

(2) The gelatinous compound for skin described in claim 1, wherein the compositional ratio of the solvent is 99.7 wt% or less of the entire composition.

### 3. Detailed Description of the Invention

#### (Industrial Field of Application)

The present invention relates to a gelatinous compound for skin. The purpose of the present invention is to provide a gelatinous composition for skin that can be used as a pack or massage agent. When applied using the fingers or palm of the hand, it goes on without running and feels good on the skin. When applied as a pack, the heat from the hydration reaction with the water content of the skin generates heat. When the gelatinous compound for skin is used in a massage, the force of the massage is tangibly transferred to the skin without excessive peeling of the corneum due to friction.

(Prior Art)

Skin generally comprises the stratum corneum consisting of hard protein, the epidermis covering the stratum corneum, tough fiber tissue and elastic subcutaneous tissue. This is extremely important to the functioning of the human body.

The skin performs protective, temperature-regulating, sense, respiratory, secretive and absorptive functions. The skin also gradually changes state as the body matures from childhood to the prime of life.

As skin ages, it begins to wither, lose elasticity and appear noticeably more wrinkled. A balanced diet and psychological stability are very important to the skin.

Another means of preserving the health of the skin is massage.

Massage stimulates the surface of the skin, which gets the blood flowing, increases metabolism, and activates skin tissue. In order to prevent excessive peeling of the corneum due to friction during massage, oily creams or lotions are used whose main component is a hydrocarbon-based oil.

However, the massage effect is not as good when one of these massage creams or massage lotions is used because insufficient load is applied to the skin.

Also, these massage creams and massage oils do not sufficiently rinse off because their main component is an oil. After use, the skin remains oily to the touch.

A pack temporarily raises skin temperature, increases blood flow and boosts the metabolism of skin tissue, and there is interest in developing a good massage agent that combines these functions.

#### (Means of Solving the Problem)

The present invention is a gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater. This is successful at eliminating the shortcomings of the prior art.

#### (Composition of the Invention)

The main component in the solvent used in the present invention is a polyhydric alcohol such as propylene glycol, glycerin, diglycerin and dipropylene glycol.

These polyhydric alcohols feel warm to the touch when used because of heat from the hydration reaction with the water content of the skin.

The concentration of polyhydric alcohol should range between 80 and 100 wt%.

If there is less than 80 wt% in the solvent when the solvent is compounded to prepare the gelatinous composition for skin, polyhydric alcohol reacts with the water or lower alcohol used as a diluent in the solvent and heat is generated from the hydration reaction. When applied to the skin, there is no hydration reaction heat and a heat effect is not experienced.

The compositional ratio of the solvent should be 99.7 wt% or less of the entire composition.

If the amount of solvent exceeds 99.7 wt% of the entire composition, the composition does not gel properly during compounding.

In addition to the polyhydric alcohol, the solvent in the present invention can contain 0 to 20 wt% water, lower alcohol such as ethanol, isopropyl alcohol or propyl alcohol, or an organic solvent such as ethyl carbitol, ethyl cellosolve, chloroform, isopropyl myristate or isopropyl palmitate.

The anionic polymer compound used in the present invention can be polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer.

Because the non-ionic polymer compound used in the present invention is the gelling agent, a carboxyvinyl polymer is preferred.

This is because a gel produced by a carboxyvinyl polymer has many advantages. It is non-sticky, resists microbes and molds, a small amount provides high viscosity, and it is thixotropic. It is also highly stable and can be used in a wide variety of solvents containing water and different alcohols and polyhydric alcohols.

The amount of anionic polymer compound used in the present invention should be 0.1 to 10 wt% of the overall composition.

If less than 0.1 wt% is used, gel formation is poor. If more than 10 wt% is used, solubility and dispersability decline and the composition becomes difficult to prepare. The gel viscosity is also too high and the composition does not feel good to the touch.

After the anionic polymer composition has been dissolved and dispersed in the solvent, an appropriate neutralizer is added.

A neutralizer is added to neutralize the anionic polymer composition and provide a more viscous gel. This can be an inorganic alkali compound or an organic alkali compound.

Specific examples of inorganic alkali compounds include sodium hydroxide, calcium hydroxide and potassium hydroxide. Specific examples of organic alkali compounds include monoethanol amine, diethanol amine, triethanol amine, aminomethyl propanol and aminomethyl propanediol.

The amount of neutralizer added should be enough to cause the anionic polymer compound to gel. The actual amount depends on the type of anionic polymer compound and the amount of anionic polymer compound used.

The water-soluble non-ionic polymer compound used in the present invention is preferably hydroxyethyl cellulose, xanthan gum, polyvinyl alcohol or polyvinyl pyrrolidone. Among these, hydroxyethyl cellulose and polyvinyl pyrrolidone are recommended.

By compounding the water-soluble non-ionic polymer compound with the anionic polymer composition in a solvent whose main component is a polyhydric alcohol, sufficient load can be applied during a massage to the skin without causing excessive peeling of the corneum due to friction.

The amount of water-soluble non-ionic polymer compound used in the present invention should be 0.1 to 10 wt% of the overall composition.



If less than 0.1 wt% is used, the massage effect of the resulting gelatinous composition for skin is not sufficient. If more than 10 wt% is used, it becomes difficult to stir because of solubility. Therefore, less than 10 wt% is used.

In the present invention, additives such as fragrance and pigment are added in the usual way. Polyethylene particles can be added to improve the feel of the composition on the skin.

The following is a clearer explanation of the effect of the present invention with reference to working examples of the present invention.

(Working Examples 1-7 and Comparative Examples 1-3)

The gelatinous compositions for skin in Working Examples 1-7 and Comparative Examples 1-3 were prepared as shown in Table 1 through Table 4.

The gelling effect, heat effect and massage effect of these gelatinous compositions for skin were then tested in the following manner.

After applying 5 g of the compositions to the inside skin of the upper arm on 10 test subjects (19 to 30 years old) and allowing them to stand for several minutes, the arms were massaged for several minutes more. The subjects were then interviewed and numeric values were assigned to the various effects.

Average values were then calculated.

The evaluation process used a five-value scale: -2, -1, 0, +1, +2.

In the final evaluation, the averages were assigned symbols: a result between -1 and -2 was assigned x (poor), between 0 and -1 was assigned Δ

(somewhat poor), between 0 and +1 was assigned ○ (good), and between 1 and 2 was assigned ● (very good).

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Table 1 (Working Example 1)

|  |           |
|--|-----------|
| Carboxyvinyl Polymer   | 0.4       |
| Polyvinyl Pyrrolidone  | 3.0       |
| Glycerin   | 90.0      |
| Polyoxyethylene (20) Polyoxypropylene (6) Decyltetradecylether | 0.2       |
| Fragrance  | 0.2       |
| Methyl p-Aminobenzoic Acid                                     | 0.2       |
| Triethanol Amine   | 0.4       |
| Pigment  | Trace     |
| Purified Water   | Amount    |
|  | Remainder |
| Total  | 100.0     |

Table 2 (Working Example 2)

|  |           |
|--|-----------|
| Carboxyvinyl Polymer                     | 0.2       |
| Polyvinyl Pyrrolidone                    | 5.0       |
| Diglycerin                               | 40.0      |
| Propylene Glycol                         | 40.0      |
| Polyoxyethylene (60) Hardened Castor Oil | 0.1       |
| Fragrance                                | 0.1       |
| Methyl p-Aminobenzoic Acid               | 0.2       |
| Triethanol Amine                         | 0.2       |
| Pigment                                  | Trace     |
| Polyethylene Particles                   | Amount    |
| Purified Water                           | 5.0       |
|  | Remainder |
| Total                                    | 100.0     |

(Blank Space)

Table 3

|                              | Working Examples |           | Comparative Example |
|------------------------------|------------------|-----------|---------------------|
|                              | 3                | 4         | 1                   |
| Glycerin                     | 90.0             | 90.0      | 90.0                |
| Diglycerin                   | -                | -         | -                   |
| Propylene Glycol             | -                | -         | -                   |
| Polypropylene<br>Pyrrolidone | 1.0              | 0.1       | -                   |
| Hydroxyethyl Cellulose       | -                | -         | -                   |
| Carboxyvinyl Polymer         | 1.0              | 1.0       | 1.0                 |
| Triethanol Amine             | 1.0              | 1.0       | 1.0                 |
| Purified Water               | Remainder        | Remainder | Remainder           |

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Table 4

|                              | Working Examples |           | Comparative Example |
|------------------------------|------------------|-----------|---------------------|
|                              | 5                | 6         | 2                   |
| Glycerin                     | -                | -         | -                   |
| Diglycerin                   | -                | -         | -                   |
| Propylene Glycol             | 80.0             | 80.0      | 80.0                |
| Polypropylene<br>Pyrrolidone | -                | -         | -                   |
| Hydroxyethyl Cellulose       | 1.0              | 1.0       | 1.0                 |
| Carboxyvinyl Polymer         | 0.5              | 0.1       | -                   |
| Triethanol Amine             | 0.5              | 0.1       | -                   |
| Purified Water               | Remainder        | Remainder | Remainder           |

(Blank Space)

Table 5

|                           | Working Examples |           | Comparative Example |
|---------------------------|------------------|-----------|---------------------|
|                           | 7                | 8         | 3                   |
| Glycerin                  | -                | -         | -                   |
| Diglycerin                | 99.7             | 80.0      | 70.0                |
| Propylene Glycol          | -                | -         | -                   |
| Polypropylene Pyrrolidone | 0.1              | 0.1       | 0.1                 |
| Hydroxyethyl Cellulose    | -                | -         | -                   |
| Carboxyvinyl Polymer      | 0.1              | 0.1       | 0.1                 |
| Triethanol Amine          | 0.1              | 0.1       | 0.1                 |
| Purified Water            | Remainder        | Remainder | Remainder           |

(Blank Space)

Table 6

|             | Working Examples |   |   |   |   |   |   |   | Comparative Examples |   |   |
|-------------|------------------|---|---|---|---|---|---|---|----------------------|---|---|
|             | 1                | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1                    | 2 | 3 |
| Gel         | ○                | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○                    | x | ○ |
| Heat Action | ○                | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○                    | ○ | x |
| Massage     | ○                | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Δ                    | Δ | Δ |

(Effect of the Invention)

As described above, the present invention is a gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater. As a result, it has the following effects.

When applied using the fingers or palm of a hand after pouring it out from the mouth of a bottle, it covers the skin without becoming runny.

When covering the skin, it feels good and not greasy. The heat generated by the hydration reaction with the water content of the skin makes the skin warm.

During the massage, the force of the massage is transferred tangibly to the skin without causing excess peeling of the corneum due to friction.

Agent      Yoshihiro KIYOHARA, Patent Attorney [seal affixed]